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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,057	11/21/2000	Michael Brines	10165-010-999	5119

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/717,057	BRINES ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 05 October 2005 has been entered in full. Claims 2-7 and 9 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement(s)(IDS) filed (05 October 2005) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Withdrawn Objections And/Or Rejections

The rejection to claims 2-7 and 9 under 35 U.S.C. 112, first paragraph, scope of enablement, as set forth at pages 2-5 of the previous Office Action (05 April 2005), is *withdrawn* in view of the literature submitted in the IDS by Applicant (05 October 2005).

The provisional rejection to claims 5-7 and 9 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7, 8, 11 and 12 of copending Application No. 09/717,053, as set forth at pages 5-6 of the

previous Office Action (05 April 2005), is *withdrawn* in view of the submitted Terminal Disclaimer (05 October 2005).

The provisional rejection to claims 4-7 and 9 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 17, 18-22 of copending Application No. 09/716,960, as set forth at pages 5-9 of the previous Office Action (05 April 2005), is *withdrawn* in view of the submitted Terminal Disclaimer (05 October 2005).

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

Claims 2-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method of enhancing the function of normal, damaged or injured central nervous system tissue in a mammal, **wherein the damage or injury is caused by blunt trauma, stroke or cerebral hypoxia-ischemia**, comprising administering peripherally to a mammal in need thereof a peripherally effective, non-toxic effective amount of recombinant erythropoietin for enhancing central nervous tissue function; (claim 2) so that the associative learning or memory in/of the mammal is enhanced; (claim 3) so that cognitive function is enhanced;

a method of enhancing the function of normal, damaged or injured excitable tissue in a mammal, comprising administering peripherally to a mammal in need thereof a peripherally effective non-toxic effective amount of recombinant erythropoietin for

enhancing excitable tissue function, wherein said excitable tissue is **central nervous tissue** (claim 4);

a method of enhancing the function of normal, damaged or injured excitable tissue in a mammal, **wherein the damage or injury is caused by diabetic neuropathy or myocardial infarction**, comprising administering peripherally to a mammal in need thereof a peripherally effective, non-toxic effective amount of recombinant erythropoietin for enhancing excitable tissue function
(claims 5-7, 9);

does not reasonably provide enablement for the instant claims as recited.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for part of this rejection is set forth at pages 2-5 of the previous Office Action (05 April 2005).

Applicant invites the Examiner's attention to the following studies published subsequent to the filing date of the present application, which demonstrates the claimed methods are enabled. Applicant cites Lu *et al.,* 2005, Journal of Neurotrauma 22(9):1011-1017; Mogensen *et al.,* 2004, Pharmacology, Biochemistry and Behavior 77:381-390; Kumral *et al.* 2004, Behavioral Brain Res. 153:77-86; Ehrenreich *et al.,* Molecular Psychiatry (2003), 1-13; van der Meer *et al.,* 2005, JACC 46(1): 125-33 and Keswani *et al.,* 2004, Ann Neurol 56:8 15-826.

The Examiner will discuss Applicant's statements regarding Lu, Mogensen, Kumral and Ehrenreich. Applicant argues that Lu *et al.* demonstrate that peripheral

administration of effective doses of EPO effectively enhanced the function of damaged excitable central nervous system tissue, thereby enhancing associative learning and cognitive function in rats with damaged excitable tissue. Applicant argues that Mogensen *et al.* demonstrate that the fibria-fornix transected rats, which were treated with EPO had a more transient and limited impairment in comparison to the saline treated fibria-fornix group. Applicant argues that Kumral *et al.* demonstrate that peripheral administration of effective doses of EPO effectively enhanced the function of damaged excitable central nervous system tissue (hypoxia-ischemia), thereby enhancing associative learning and cognitive function in rats with damaged excitable tissue. Applicant argues that Ehrenreich *et al.* demonstrate that the results of the conditioned taste aversion model in rats indicate that peripheral administration of effective doses of EPO may effectively enhanced the function of damaged excitable central nervous system tissue, thereby enhancing associative learning and cognitive function in rats with damaged excitable tissue in diseases using similar pathways, such as schizophrenia.

The scope of patent protection sought by Applicant as defined by the claims fails to bear a reasonable correlation with the scope of enabling disclosure set forth in the specification. Kumral *et al.* teach that hypoxia-ischemic brain injury is an important cause of neonatal mortality and subsequent sequelae such as cerebral palsy, mental retardation, learning disability and epilepsy. Kumral *et al.* do not teach that hypoxia-ischemic brain injury in rats is an experimental animal model for those diverse conditions (cerebral palsy, mental retardation, learning disability and epilepsy). Claims 2

and 3, as recited, encompass enhanced associative learning and cognitive function upon EPO administration in any type of injury or damage to central nervous system tissue. Enhanced associative learning and cognitive function upon EPO administration has been only demonstrated in certain animal models. Furthermore, the specification teaches "excitable tissue" to include neuronal tissue. Claim 4, as recited, encompasses enhanced function upon EPO administration in all normal, damaged or injured neuronal tissue. The hypoxia-ischemic brain injury animal model is not applicable to all damaged or injured neuronal tissue.

Ehrenreich *et al.* teach that there are no satisfying animal models available for schizophrenia. Ehrenreich *et al.* teach that some behavioral phenomena resulting from information processing disturbances in schizophrenia patients can also be observed in animals, for example, poor associative learning or disruption of latent inhibition, as measure with the condition taste aversion (CTA) paradigm (page 2, 1st column, 2nd paragraph and page 9, 2nd column, 2nd paragraph). The CTA animal model tests an animal's ability for learning to associate illness with a novel taste stimulus, such that the animal avoids the novel taste upon subsequent re-exposure to the novel stimulus. The CTA animal model does not encompassed injured or damaged excitable tissue.

Therefore, in view of the submitted literature, the Examiner has indicated that the enabled scope of the instant claims is: "a method of enhancing the function of normal, damaged or injured central nervous system tissue in a mammal, wherein the damage or injury is caused by blunt trauma, stroke or **cerebral hypoxia-ischemia**....so that the associative learning or memory in/of the mammal is enhanced or so that cognitive

function is enhanced" and "a method of enhancing the function of normal, damaged or injured excitable tissue in a mammal, ...wherein said excitable tissue is **central nervous tissue"**.

Lastly, Applicant discusses van der Meer and Keswani. Applicant argues that van der Meer demonstrates that peripheral administration of EPO enhances cardiac function in a rat model of post-myocardial infarction (MI). Applicant argues that Keswani demonstrates that EPO enhanced the function of damaged excitable peripheral nervous system tissue, experiencing axonal degeneration. Applicant's arguments have been fully considered and are deemed partly persuasive. The specification teaches "excitable tissue" to also include cardiac tissue. Claims 5-7 and 9, as recited, encompass enhanced function of any type of injury or damage to any neuronal or cardiac tissue upon EPO administration. Enhanced function of injured or damaged tissue upon EPO administration has been only demonstrated in certain animal models. Therefore, in view of the submitted literature, the Examiner has indicated that the enabled scope of the instant claims is, "a method of enhancing the function of normal, damaged or injured excitable tissue in a mammal, wherein the damage or injury is caused by diabetic neuropathy **or myocardial infarction"**.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
12/23/05

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
AU1647

1/9/06